California Medical Device Recall Information

Recall Name
Thoratec Corporation Issues Urgent Medical Device Correction Letter for HeartMate II LVAS to Prevent Advisory Alarms and Potential Injury

Recall Date	Product Description	Recalling Firm	Recall Reason
09/14/15	HeartMate II LVAS "Pocket" System Controller	**Thoratec Corporation** Pleasanton, CA	*Certain advisory alarms, associated with expiration of the system backup battery, have resulted in patients deciding to attempt a System Controller exchange. Injuries and deaths were reported in patients who were unable to connect to their back up System Controller in a timely manner.* ***For all advisory ("yellow wrench") alarms, patients should first call their hospital contact for instructions.*** ***Do not attempt to replace the System Controller unless instructed by the hospital.***
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	**All** Serial Numbers that start with **"PC"** (i.e. "Pocket Controller")	**CA**, nationwide	N/A

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm462627.htm